DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 5, 2014

Cook Incorporated
Mr. Sean Spence, RAC
750 Daniels Way
Bloomington, IN 47404

Re: K141818
Trade/Device Name: Turbo-Ject PICC Sets
Regulation Number: 21 CFR 880.5970
Regulation Name: PICC Sets
Regulatory Class: II
Product Code: LJS
Dated: July 3, 2014
Received: July 7, 2014

Dear Mr. Spence:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
TBD K141818

Device Name
Turbo-Ject® Peripherally Inserted Central Venous Catheter (PICC)

Indications for Use *(Describe)*

Turbo-Ject Peripherally Inserted Central Venous Catheter (PICC) Sets and Trays are intended for short- or long-term use for venous pressure monitoring, blood sampling, administration of drugs and fluids, and for use with power injectors for delivery of contrast in CT studies. The Turbo-Ject PICC is indicated for multiple injections of contrast media through a power injector. The maximum pressure limit setting for Power Injectors used with the Turbo-Ject PICC may not exceed 325 psi and the flow rate may not exceed the maximum flow rate indicated.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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10.0 510(k) SUMMARY

Turbo-Ject® PICC Sets
21 CFR §807.92
Date Prepared: 3 July 2014

Submitted By:

Applicant:	Cook Incorporated
Contact:	Sean Spence, RAC
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x105127
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Turbo-Ject® PICC Sets
Common Name:	PICC Sets
Classification Name:	Catheter, intravascular, therapeutic, long-term greater than 30 days
Regulation:	21 CFR §880.5970
Product Code	LJS

Predicate Devices:

- K072625, Turbo-Ject Peripherally Inserted Central Venous Catheter (PICC)
- K111244, Turbo-Ject® PICC Set
- K132334, Turbo-Ject® Peripherally Inserted Central Venous Catheter Set
- K132885, Turbo-Ject® Peripherally Inserted Central Venous Catheter Set

Device Description:

The 3.0, 4.0, 5.0, and 6.0 Fr Turbo-Ject PICC Sets with various lumen configurations are radiopaque polyurethane peripherally inserted central venous catheters for short- or long-term use, and can be inserted through a Peel-Away® introducer or over-the-wire. The set components may include the PICC, obturator, Peel-Away® introducer, entry needles, wire guide, and other convenience components. The set is supplied sterile and is intended for one-time use.

Intended Use:

Turbo-Ject Peripherally Inserted Central Venous Catheter (PICC) Sets and Trays are intended for short- or long-term use for venous pressure monitoring, blood sampling, administration of drugs and fluids, and for use with power injectors for delivery of contrast in CT studies. The Turbo-Ject PICC is indicated for multiple injections of contrast media through a power injector. The maximum pressure limit setting for power injectors used with the Turbo-Ject PICC may not exceed 325 psi and the flow rate may not exceed the maximum flow rate indicated.

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Comparison to Predicates:

It has been demonstrated that the subject Turbo-Ject® PICC Sets are comparable to the predicates. Both are intended for short- or long-term use for venous pressure monitoring, blood sampling, administration of drugs and fluids, and for use with power injectors for delivery of contrast in CT studies. In addition, the subject devices and predicate are substantially equivalent in terms of design.

Technological Characteristics:

The following tests were performed to demonstrate that the subject Turbo-Ject® PICC Set met applicable design and performance requirements and support a determination of substantial equivalence.

- ISO 10555-1:2013, Force at Break – Testing demonstrated the proposed device met the predetermined acceptance criteria following accelerated aging
- ISO 10555-1:2013, Liquid Leakage – Testing demonstrated the proposed device met the predetermined acceptance criteria following accelerated aging
- ISO 10555-1:2013, Air Leakage – Testing demonstrated the proposed device met the predetermined acceptance criteria following accelerated aging
- Static Burst Testing – Testing demonstrated the proposed device met the predetermined acceptance criteria following accelerated aging
- ISO 10993-1:2009, Biocompatibility – Testing demonstrated the proposed device met the predetermined acceptance criteria. The following test results were considered:
    - Cytotoxicity, Sensitization, Irritation, Systemic Toxicity (Acute), Subchronic Toxicity, Genotoxicity, Implantation, Hemocompatibility
    - In addition to those required tests, SC5b-9 and C3a Complement Activation, ASTM Partial Thromboplastin Time, and Materials Mediated Rabbit Pyrogen were preformed

Conclusion:

The results of these tests provide reasonable assurance that the Turbo-Ject® PICC Sets are as safe and effective as the predicate devices and support a determination of substantial equivalence.